

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>			1. CONTRACT ID CODE	PAGE OF PAGES 1   4
2. AMENDMENT/MODIFICATION NO. 0002	3. EFFECTIVE DATE 05/23/05	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (if applicable)	
6. ISSUED BY DHHS/OPHEP/ORDC 200 Independence Ave, SW, SW, ROOM 636G Washington, D.C. 20201	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE	
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)		(X)	9A. AMENDMENT OF SOLICITATION NO. ORDC-V&B-05-04	
		x	9B. DATED (SEE ITEM 11) 04/29/05	
			10A. MODIFICATION OF CONTRACT/ORDER NO.	
			10B. DATED (SEE ITEM 11)	
CODE	FACILITY CODE			

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended,  is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:  
 (a) By completing items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

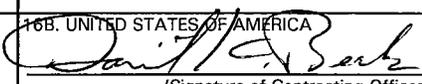
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor  is not,  is required to sign this document and return \_\_\_\_\_ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this amendment is to clarify various sections of RFP-ORDC-V&B-05-04, provide a copy of the pre-proposal conference presentation presented on May 20, 2005, and to provide answers to questions.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) David K. Beck
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	16B. UNITED STATES OF AMERICA  (Signature of Contracting Officer)
15C. DATE SIGNED	16C. DATE SIGNED 05/23/05

**Amendment 0002**

1. In Block 8 of the Cover Page, the text “Electronic File Size: NTE 5 mega-bytes” is removed.

2. In the table of Contract Line Item Numbers (CLINS) in paragraph B.4, the text in the Supplies/Services Column for CLIN 0004 is revised to read as follows:

**“Feasibility plan to manufacture, formulate, fill, and finish at least 150 million doses of monovalent influenza vaccine (milestone 4).”**

3. After the table of Contract Line Item Numbers (CLINS) in paragraph B.4, the following note is added:

**“Note. For purposes of this RFP, “United States” and “U.S.” are defined to include the 50 states, the District of Columbia, and Puerto Rico.”**

4. In paragraph C.1, in the fourth paragraph following the heading “Significance and Objectives,” the fourth sentence is revised to read as follows:

**“Portions of the vaccine product development plan may be conducted outside of the U.S. except pivotal clinical studies, which will be used to support a BLA product submission.”**

5. In the table of Contract Deliverables in paragraph F.3, the text in the Deliverable Column for Milestone 4 is revised to read as follows:

**“Feasibility plan to manufacture, formulate, fill, and finish at least 150 million doses of monovalent influenza vaccine.”**

6. Section H – Special Contract Requirements, is revised as follows:

The text in paragraph H.15 on Intellectual Property is removed and the heading is revised to read **“Reserved”**.

7. In the table of general clauses under Sec. I.1, the following clause is added since funding for this acquisition is not expected until October 1, 2005 at the earliest:

**FAR 52.232-18, Apr 1984, Availability of Funds**

8. In Section J – List of Attachments, the date following “3. Proposal Intent Response Sheet (Submit on/before:” is changed from May 9, 2005 to **“May 27, 2005”**.

9. In Section J – List of Attachments, the first attachment on Packaging/Delivery/Electronic Submission of the Proposal, is revised as follows:

a. Lines 6 to 9 are revised to read as follows:

**“You will submit your proposal in two formats: paper and electronic.**

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- **“The paper proposal with original signatures is the official, legally binding copy. There are no acceptable substitutes.**
- **“The electronic version of the proposal (CD or USB) is for the benefit of ORDC. The electronic version may or may not be used for review, at the discretion of ORDC.”**

b. The paragraph on Electronic Submission is revised to read as follows: **“In addition to the paper submission, you are requested to submit your proposal on CD or USB.”**

c. In the table “Number of Copies”, under the Column “File Size”, the text in the first three rows is revised to read: **“Electronic file size is unlimited; however, all electronic submissions shall be on a CD or USB.”**

d. In the table “Number of Copies”, under the Column “Number of Copies”, the text in the last line for “Business Proposal” is corrected to read as follows: **“Five (5) bound copies.”**

10. In Section J – List of Attachments, the second attachment on How to Prepare and Submit an Electronic Proposal, is revised as follows:

a. The heading “Submission of “Proposal Intent Response Sheet”” and the paragraph following the heading are removed. (This change affects only the instructions about online proposal transmission. The change does not affect instructions for submitting a Proposal Intent Response Sheet.)

b. The heading “Log-In / Transmission Instructions” and the paragraphs following the heading are removed.

11. In Section J – List of Attachments, Instruction 5 in the attachment “Breakdown of Proposed Estimated Cost (Plus Fee) and Labor Hours” is revised to read as follows:

**“Offerors may use either the spreadsheet on page 38 (in PDF) or an Excel spreadsheet that uses similar columns and rows.”**

12. Section L – Instructions, Conditions, and Notices to Offerors, is revised as follows:

a. Under Item 23, Technical Proposal Instructions, the last sentence of the last paragraph is revised to read as follows:

**“The technical proposal, (excluding the section entitled past performance) should not exceed to 40 single spaced, single sided, 8 1/2 by 11 inch pages of 10 or 12-pitch type, excluding appendices and resumes of key personnel.”**

b. In Item 26, the reference to Section B.3 is corrected to read **“Section B.4”**.

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13. Section M – Evaluation Factors for Award, is revised as follows:

a. In Section M, Evaluation Factors for Award, under paragraph 1, General, the last paragraph and the heading “Intellectual Property” are removed.

b. The next to last paragraph under paragraph M.1, Mandatory Criteria for Eligibility, is revised to read as follows:

**“The Offeror’s proposal must indicate that the Offeror will submit by no later than six (6) months after contract award an IND, if not filed already, with the FDA for the clinical development program and Phase I clinical safety and immunogenicity testing of the Offeror’s cell- or recombinant-based influenza vaccine candidates. If the IND has been filed, the proposal must provide documentation regarding the filing.”**

c. In paragraph M.2, under subparagraph 1, Methodology and Approach, the following subparagraph is added:

**“G. The proposal must describe the extent to which the Offeror has unencumbered access to intellectual property necessary to fulfill its obligations under the contract. The U.S. Government expects and intends to require that the Offeror will take all steps necessary to secure access to all intellectual property, know-how and tangible materials. Accordingly, the U.S. Government requires written evidence of the extent to which the Offeror has secured access to such intellectual property, know-how and tangible materials to suitable cell culture and/or recombinant DNA technology unencumbered by legal or patent constraint.”**

d. In paragraph M.3., Past Performance Information, the first sentence of subparagraph 2 is revised to read as follows:

**“The offeror shall provide a list of the last three (3) contracts completed during the past three years and the last (3) contracts awarded currently in process that are similar in nature to the solicitation work scope.”**